## REMARKS

Docket No.: 37998-237420

#### Introduction

Claims 11-13, 16-18, and 25 are pending. Claims 11-13, 16-17 and 25 have been amended. Support for these amendments can be found throughout the specification, for example, in the claims as filed and at paragraphs [0024]-[0028] and [0039].

Claims 1-10, 14-15, 19-24, and 26 have been cancelled without prejudice to the subject matter disclosed therein. Applicant expressly reserves the right to pursue the subject matter of these claims via rejoinder or in another application.

# Claim Objections

The claims have been amended. These objections are believed moot in light of the amendments. Withdrawal of the objections is respectfully requested.

# Rejections under 35 U.S.C. §112

#### A. First Paragraph

The Examiner has rejected claims 11-13, 16-18, and 25 under the first paragraph of 35 U.S.C. §112 as allegedly lacking enablement and written description for the perceived claim scope. Applicants traverse.

Claim 11 has been amended to respond to the Examiner's concerns regarding the claim scope. Amended claim 11 recites that the isolated HF-chondroosteomodulin (COM) polypeptide or derivatives thereof consist of the core amino acid sequence of SEQ ID NO:1. Applicant provides the claimed sequence in paragraph [0024] and describes uses for the sequence through out the examples. One of skill in the art would be able to practice the claimed invention without undue experimentation as well as recognize that Applicant was in possession of the claimed invention at the time of filing.

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Further, regarding the claimed derivatives consisting of the core structure of SEQ ID NO:1, the amended claim now requires that derivatives of SEQ ID NO:1 must activate the GORI-28 receptor consisting of the amino acid sequence of SEQ ID NO:2. Applicant provides a full sequence for the target receptor, an assay for conducting these tests (e.g., FLIPR), and an example of how to conduct such a test (e.g., example 3). Derivatives of SEQ ID NO:1 can be prepared using methods well known to one of skill in the art and then tested for activity without undue experimentation using the methods Applicant has described.

For at least these reasons, the rejections of claim 11 and its dependent claims (12-13, 16-18, and 25) under 35 U.S.C. §112 first paragraph are improper. Applicant respectfully requests that they be withdrawn.

# B. Second Paragraph

The Examiner has rejected claims 16, 17, and 25 under the second paragraph of 35 U.S.C. §112 as allegedly being indefinite. Applicants traverse.

Claims 16, 17, and 25 have been amended. This rejection is believed moot in view of the amendments. Withdrawal of this rejection is respectfully requested.

# Rejection under 35 U.S.C. §101

The Examiner has rejected claims 11-13 and 25 under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. Applicants traverse.

The claims have been amended to include the phrase "isolated." This rejection is believed moot in view of the amendments. Withdrawal of this rejection is respectfully requested.

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Rejections under 35 U.S.C. §102

A. International Publication WO/9855508A2

The Examiner has rejected claims 11, 12, 16 and 25 under 35 U.S.C. §102(b) as allegedly being anticipated by International Publication WO/9855508A2 (the '508 publication). Specifically, the Examiner alleges that since the word "having" in the claims can be construed as being similar in scope as the "comprising" transition the HP10433 sequence in the '508 publication anticipates the claims. Applicants traverse.

To demonstrate anticipation a publication must show each and every limitation in the claims either expressly or inherently. The claims have been amended to recite that the isolated HF-chondroosteomodulin (COM) polypeptide or derivatives thereof consist of the core amino acid sequence of SEQ ID NO. 1. This amino acid sequence is not disclosed in the '508 publication and with the new "consisting of" transition the HP10433 sequence does not anticipate the amended claim.

Further, the claims have been amended to recite that the claimed COM derivatives will activate the receptor GORI-28 consisting of the amino acid sequence of SEQ ID NO:2 in a functional test with the FLIPR system, so that a receptor activity is measured which is at least 80% of the receptor activity triggered by COM under the same conditions. The '508 publication does not disclose or provide evidence of any derivatives of the polypeptide COM having SEQ ID NO. 1 that will activate the receptor GORI-28 consisting of the amino acid sequence of SEQ ID NO:2 under the conditions claimed.

For at least the above reasons, the '508 publication does not disclose all the elements of independent claim 11 or its dependent claims (12-13, 16-18, and 25), either expressly or inherently. Therefore, the rejection under 102(b) is improper and its withdrawal is respectfully requested.

# B. U.S. Patent Publication 2003/0096299A1

The Examiner has rejected claims 11, 13, 16 and 25 under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent Publication 2003/0096299A1 (the '299 publication). Specifically, the Examiner alleges that since the word "having" in the claims can be construed as being similar in scope as the "comprising" transition the TIG2 polypeptide in the '299 publication anticipates the claims. Applicants traverse.

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To demonstrate anticipation a publication must show each and every limitation in the claims either expressly or inherently. To expedite prosecution, the claims have been amended to recite that the isolated HF-chondroosteomodulin (COM) polypeptide or derivatives thereof consist of the core amino acid sequence of SEQ ID NO. 1 and derivatives thereof do not exceed 150 amino acids. The claimed amino acid sequence and its derivatives are not disclosed in the '299 publication and with the new "consisting of" transition the TIG2 polypeptide does not anticipate the amended claim.

Further, the claims have been amended to recite that the claimed COM derivatives will activate the receptor GORI-28 consisting of the amino acid sequence of SEQ ID NO:2 in a functional test with the FLIPR system, so that a receptor activity is measured which is at least 80% of the receptor activity triggered by COM under the same conditions. The '299 publication does not disclose or provide evidence of any derivatives of the polypeptide COM having SEQ ID NO. 1 and a length of less than 150 amino acids that will activate the receptor GORI-28 consisting of the amino acid sequence of SEQ ID NO:2 under the conditions claimed.

For at least the above reasons, the '299 publication does not disclose all the elements of independent claim 11 or its dependent claims (12-13, 16-18, and 25), either expressly or inherently. Therefore, the rejection under 102(e) is improper and its withdrawal is respectfully requested.

# **CONCLUSION**

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All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 11-13, 16-18, and 25 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR §1.17, including extension of time fees pursuant to 37 CFR §1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

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Respectfully submitted,

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